Postmarket Evaluation at FDA's Center for Devices and Radiological Health

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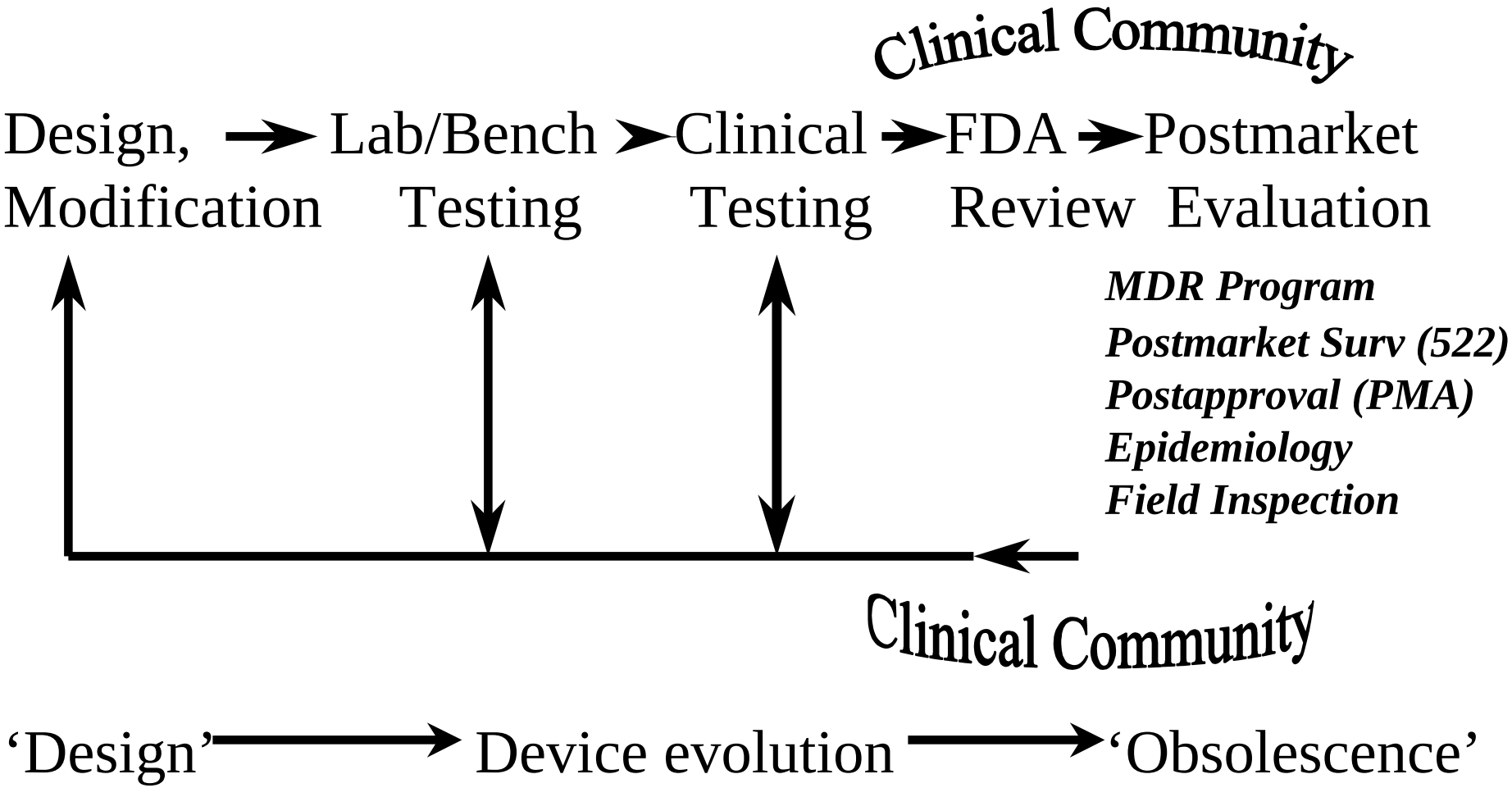
- ***Describe a few of the methods of device postmarket evaluation at CDRH***
- ***Present challenges in accomplishing postmarket evaluation***
- ***Describe some new opportunities in postmarket evaluation***

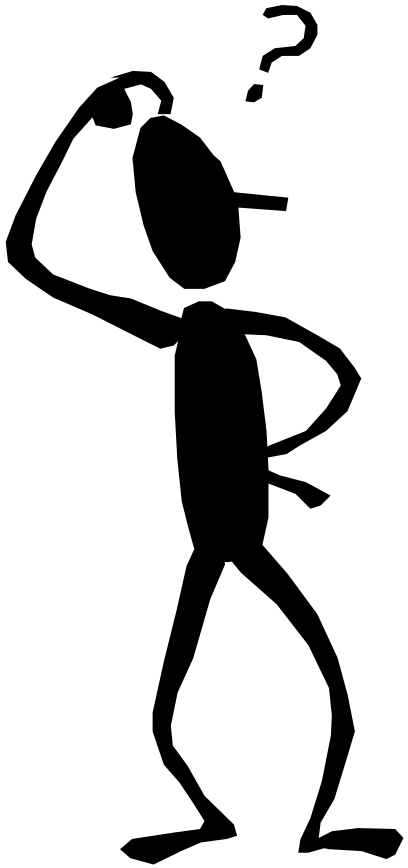
From Design to Obsolescence: Medical Devices and Center for Devices and Radiological Health, FDA



'Design' → Device evolution → 'Obsolescence'

Questions of Interest in the Postmarket Period

- Long term safety
- Performance of device in community practice
- Effects of change in user setting
- Effects of changes in technology
- Unusual pattern of adverse events



Postmarket Study Authorities: Postmarket Surveillance (Section 522) and Postapproval (PMA)

- Section 522 originally mandated in SMDA 1990 and changed in FDAMA 1997
- Postapproval refers to PMA products (condition of approval studies); 522 covers Class II or III products whose failure may present a public health problem
- Both authorities are seen as a complement to premarket

Postmarket Surveillance Philosophy

- Focus PMS on device areas with greatest potential
- Develop criteria to require PMS: allows discretion for FDA
- Development and availability of “useful” postmarket data

Criteria for Postmarket Surveillance Study

- The critical public health question
  - Can result from:
    - "For cause"
    - New clinical indications or uses
    - Evolution of technology
- Consideration of other postmarket strategies
- Practicality and feasibility of conduct
- How will data be used?
- Guidance issued; developing regulation

Postmarket Surveillance Study Design Approaches

- Detailed review of complaint history/literature
- Non-clinical testing of device
- Use of existing data sets, e.g., Medicare
- Telephone or mail follow up of patients
- Use of product registries
- Case control studies
- Randomized trials

Frustrations in the Postmarket Period

- Rapid evolution of technology make studies obsolete
- Lack of incentives for the industry
- Lack of interest in the clinical community
- Lack of clearly specified public health question

Two New Postmarket Opportunities

- Joint meeting between FDA, American College of Cardiology, and Manufacturers
- Medical Device Surveillance Network (MeDSuN)

FDA, ACC, Industry Workshop

- Session at ACC meeting in March 1999
- Potentially duplicative data collection efforts in cardiovascular arena
- Example of implementation of FDAMA to expand approaches for postmarket
- Pre-post balance and least burdensome opportunities

THE MEDICAL DEVICE SURVEILLANCE NETWORK (MeDSuN)

WHY CHANGE USER REPORTING?

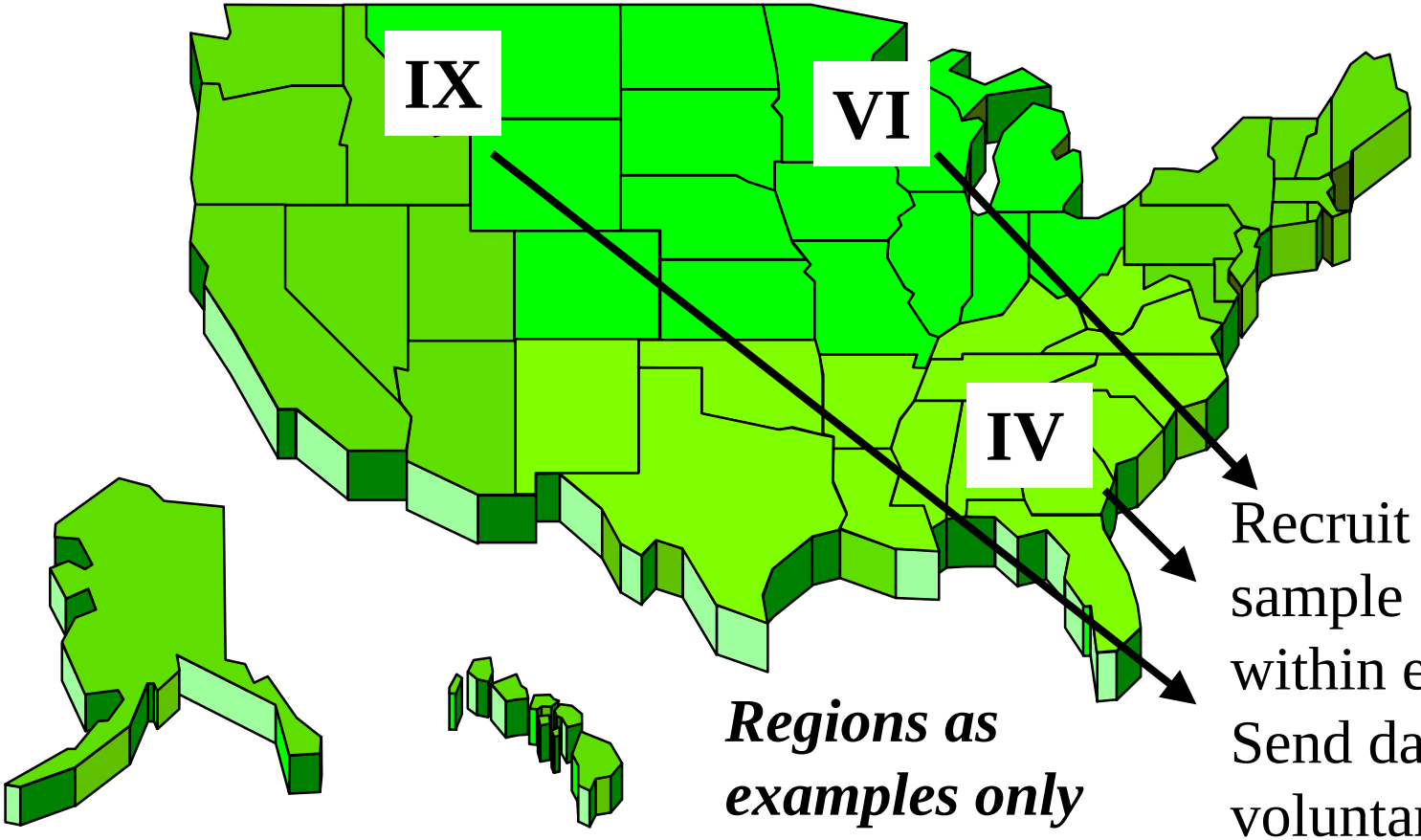
- **Underreporting / lack of quality data**
- **Lack of connection to clinical facilities**
- **Changes in conceptualization**
- **FDAMA**

Where Are We Now?

- **Pilot of 24 hospitals for one year completed and highly successful.**
- **Planning to implement larger “Phase 2” pilot - 50 facilities each from 3 regions of country**
- **Request for Proposal for contractor to aid in Phase 2 development will be issued when funding received.**
- **Regulation to implement national program will be issued following Phase 2 experience.**

FDA: Management, Analysis, and Action

Coordinating Center: Maintain uniformity and quality control; Materials development; Advisory Group



Regions as examples only

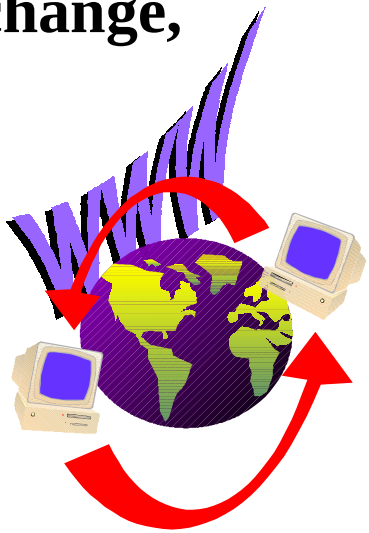
Recruit probability sample of facilities within each region; Send data; Grassroots voluntary reporting

MeDSuN Impact on Manufacturers

- **Manufacturer reporting responsibilities remain unchanged.**
- **MeDSuN participating user facilities will send adverse event reports to manufacturers with more useful information about the device-related incident.**
- **Manufacturers able to be more proactive in preventing device-related deaths and serious injuries.**

The Future of MDR and PS

- **Medical Device Reporting**
  - **Summary reporting**
  - **MeDSuN**
  - **Electronic interchange, perhaps via WWWeb**
  - **Integration with Q.S.R.**
  - **International harmonization**



- **Postmarket Surveillance**
  - **Wider variety of design approaches**
  - **More collaboration with industry and clinical community**
  - **Expanded access to different data sources, e.g., registries**